

REMARKS

Claims 16-25, 36, 41-42, 44-47 and 55-84 were pending as of the issuance of the Office Action. Claims 17-19, 21-24, 36, 41, 42, 44-47, 55-65 and 67-84 were withdrawn as set forth in the Office Action. Claims 16, 20, 25 and 66 stand rejected. By the current Amendment to Claims, claims 16, 20, 21, 22, 25, 36, 62 and 79 have been amended, new claims 85-88 have been added and claims 17, 61, 65, 73, 81 and 84 have been cancelled, without prejudice.

Support for the amendments to the claims and the introduction of new claims can be found throughout the specification and in the claims as originally filed. Specifically, the amendments to claims 16, 20, 21 and 36 can be found throughout the specification, for example, at page 10, lines 2-5 and page 29, lines 4-6, and in the claims as originally filed, for example, claims 17 and 22. In addition, support for new claim 85 can be found throughout the specification, for example, at page 10, lines 5-8 and page 29, lines 7-10, and in the claims as originally filed, for example, claims 21 and 22. Support for new claim 86 can be found throughout the specification, for example, at page 9, lines 18-19 and page 28, lines 11-14, and in the claims as originally filed, for example, claims 21 and 22. Support for new claim 87 can be found throughout the specification, for example, at page 9, lines 24-26 and page 28, lines 18-20, and in the claims as originally filed, for example, claim 22. Lastly, support for new claim 88 can be found throughout the specification, for example, at page 9, line 28 to page 10, line 2 and page 29, lines 1-3, and in the claims as originally filed, for example, claim 22.

No new matter has been added by the amendments to the claims or the introduction of new claims. Applicants respectfully request that the aforementioned amendments be entered. Applicants note that the foregoing amendments have been made solely in order to expedite examination and in no way should be construed as acquiescence to the validity of the rejections set forth in the Office Action. Applicants reserve the right to pursue the claims as originally filed in this or subsequently filed applications. Following entry of the foregoing amendments, claims 16, 18-25, 36, 41-42, 44-47, 55-60, 62-64, 66-72, 74-80, 82, 83 and 85-88 will be pending.

Rejection of Claims under 35 U.S.C. § 102(b) (Vandenbark)

The pending claims have been rejected as being anticipated by International Publication No. WO96/01329 (hereinafter referred to as “Vandenbark”) on the ground that Vandenbark allegedly

teaches in Figure 4A the peptide CSF A10 of the sequence DSTRALYF... This sequence meets the limitations of the rejected claims. X1, X3, X4 and X5 are each a natural amino acid and X2 is serine. Applicants argue that the sequence is not isolated as is required by the instant claims; however, the sequence is specifically identified in the cited Figure 4A. Applicants have not shown cited support for their argument that the sequence is not isolated. Furthermore, if the '1329 sequence was not isolated or clearly identified for one of skill in the art to see, then Applicants have not established why the '1329 reference would list it as an individual sequence versus listing it as a portion of a larger sequence.

Applicants respectfully disagree for the reasons of record. Notwithstanding the foregoing, solely in the interest of expediting examination and in no way acquiescing to the validity of the outstanding rejection, Applicants have amended the pending claims, thereby rendering the foregoing rejection moot. Indeed, Applicants submit that Vandembark fails to teach the claimed peptides as pending. In part, the residue corresponding to X⁵ in the Vandembark peptide is tyrosine, which is not permitted by each of the pending claims. For example, each of claims 16, 20 and 21 specify that X⁵ is selected from the group consisting of glycine, isoleucine, norleucine, norvaline, cyclohexylalanine (Cha), phenylalanine and 1-naphthylalanine (1Nal). Accordingly, the sequence taught by Vandembark is distinct from the sequences of the present invention and therefore, Vandembark fails to anticipate the pending claims. In view of the foregoing, reconsideration and withdrawal of the outstanding rejection is respectfully requested.

Rejection of Claims 20 and 66 under 35 U.S.C. § 102(b) (Kisfaludy et al.)

Claims 20 and 66 have been rejected as being anticipated by Kisfaludy *et al.* (Pept. Proc. Eur. Pept. Symp. 14th (1976) pages 239-249) (hereinafter referred to as "Kisfaludy") on the ground that Kisfaludy allegedly "teach[es] a peptide fitting the instantly claimed generic formula of SEQ ID NO: 2, wherein the two C-terminal amino acid residues are reversed (see page 243 Table 2, peptide 111-117)."

Applicants respectfully disagree. Applicants submit that peptide 111-117 referenced by the Examiner refers to the following molecule: ¹¹¹Ser(Bzl)-Met-Arg(Tos)-Ala-Leu-Phe-Gly¹¹⁷-OH. Applicants submit that Kisfaludy fails to disclose the X² residue or the arginine residue as set forth in the pending claims. Specifically, the 111 residue (corresponding to the X² residue) and the 113 residue (corresponding to the arginine residue) are Ser(bzl) and Arg(tos)¹, respectively, which are not permitted by the pending claims. Indeed, claims 20 and 66 specify that the X² residue

¹ See, for example, the header of Table 2 on page 243 of Kisfaludy.

is either serine, alanine or the corresponding D-stereomer thereof. Accordingly, the peptide of Kisfaludy containing protected forms of serine and arginine is distinct from the claimed peptides of the present invention.

Applicants conclude that Kisfaludy fails to teach or suggest each and every element of the claimed invention as required for a proper novelty rejection in that Kisfaludy fails to teach the serine and arginine residues, or the specifically modified versions thereof, as required by the pending claims. Accordingly, Kisfaludy fails to anticipate the pending claims. In view of the foregoing, reconsideration and withdrawal of this rejection is respectfully requested.

**Provisional Rejection of Claims 16, 20, 25 and 66 Under the Judicially Created
Doctrine of Obviousness-Type Double Patenting**

The Examiner has rejected claims 16, 20, 25 and 66 as being unpatentable over claims 16-33 and 71-76 of copending U.S. Application No. 10/441,952 on the grounds that

[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because '952 claims a species which anticipates the instant claims as well as claiming generic formulas that read on the instantly claimed generic formulas. For example, '952 teaches SEQ ID NO:467 of claim 19 wherein the SEQ ID NO:467 is His-[Ser or Ala]-[Lys or Cys]-Arg-Arg-Lys-Xaa-Phe. The peptide may also be reversed at the last two amino acid residues of the C-terminal, and may be cyclic. A preferred embodiment anticipating the instant claims is SEQ ID NO:48-49, amongst others. Although considered withdrawn SEQ ID NOs:169-170 are claimed in '952 at claim 25.

Applicants respectfully disagree. Notwithstanding the foregoing, solely in the interest of expediting examination and in no way acquiescing to the outstanding rejections under the judicially created doctrine of obviousness-type double patenting, once the pending claims in the present application are formally indicated as otherwise allowable and should the Examiner maintain such rejection in view of further prosecution of each application, Applicants will submit a terminal disclaimer in compliance with C.F.R. 1.321(b) and (c), if appropriate, which will obviate these rejections.

CONCLUSION

Applicants believe that no additional fee is due with this submission. However, if the Applicants are in error, the Commissioner is authorized to charge any deficiency in the fees paid herewith, or credit any overpayment, to Deposit Account No. 12-0080, under Order No. CCI-014RCE, from which the undersigned is authorized to withdraw.

If there are any remaining issues or if the Examiner believes that a telephone conversation with Applicants' Attorney would be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned at (617) 227-7400.

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Respectfully submitted,

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